IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI CENTRAL DIVISION

CHRISTINE L. WINTER, Individually and as an Executor of the Estate of RUTH BALDWIN, Deceased,	)	
Plaintiff,	)	Case No. 06-04049-CV-C-NKL
v.	)	
NOVARTIS PHARMACEUTICALS CORPORATION,	)	
Defendant.	)	

ORDER

Plaintiff Christine L. Winter, deceased, individually and as Executor of the Estate of Ruth Baldwin, claims that Defendant Novartis Pharmaceuticals Corporation caused Baldwin to develop osteonecrosis of the jaw by producing and marketing its drugs Aredia and Zometa. Pending before the Court are Novartis's motion for partial summary judgment [Doc. # 101] and Winter's motion for summary judgment [Doc. # 105]. For the following reasons, the Court DENIES both motions.

I. Factual Background

Baldwin was a citizen and resident of Missouri. Novartis is a Delaware corporation, headquartered in New Jersey, which produced and marketed the drugs Aredia and Zometa.

Aredia and Zometa have been frequently prescribed to patients with metatastic breast cancer since the FDA approved Aredia in 1998. The FDA also approved Novartis's labeling at that time. On September 26, 2003, Novartis informed the FDA that it was changing its package insert to discuss the occurrence of osteonecrosis of the jaw in patients using bisphosphonates such as Zometa. In February 2004, at the request of the FDA, Novartis again changed its package insert to discuss the risk factors of Osteonecrosis of the jaw and to counsel against dental surgery "as recovery may be prolonged." [Doc. # 109 at 19]. In August 2004, Novartis revised this language again to discuss the risks of osteonecrosis of the jaw in more detail and to caution against dental surgery, stating: "For patients who develop ONJ [osteonecrosis of the jaw] while on bisphosphonate therapy, dental surgery may exacerbate the condition." [Doc. # 109 at 19]. The parties agree that Novartis implemented these changes, but do not agree on when these changes actually reached physicians in the field. Novartis highlighted these latest changes in a Dear Doctor Letter dated September 24, 2004, but the parties dispute whether Dr. Hueser, Baldwin's oncologist, ever received this letter.

In July 2003, Ruth Baldwin was diagnosed with recurrent breast cancer with metastases to her spine and liver. On July 24, 2003, Baldwin's oncologist, Dr. James Hueser, prescribed Aredia to Baldwin. In September 2003, Dr. Hueser changed

Baldwin's prescription from Aredia to Zometa. Baldwin received her last treatment of Zometa in October 2004. On November 11, 2004, Dr. Hueser decided to stop Baldwin's Zometa treatment because Baldwin had developed osteonecrosis of the jaw, which he believed to be an effect of Zometa. Dr. Hueser cannot recall a patient with metastes to whom he did not prescribe Aredia or Zometa prior to that point. Dr. Hueser has testified that he never read the package inserts for Aredia and Zometa while practicing as an oncologist, but that this was because Novartis produced them in a way that made them useless to a practitioner.

Dr. Douglas Miller was Baldwin's dentist from January 1998 to September 2006. On November 6, 2003, Dr. Miller extracted Baldwin's tooth # 31, and on September 9, 2004, Dr. Miller extracted Baldwin's tooth # 30. On October 25, 2004, Dr. Miller referred Baldwin to oral surgeon, Dr. Timothy Coyle, due to Baldwin's complaints of discomfort in the area of her mouth from which Dr. Miller had extracted tooth # 30. On October 26, 2004, Dr. Coyle informed Dr. Miller that Baldwin had developed osteonecrosis of the jaw from her bisphosphonate chemotherapy, precipitated by tooth extractions.

Dr. Miller has testified that had he known about the relationship between bisphosphonates and osteonecrosis of the jaw, he would have considered alternatives to tooth extraction on Baldwin. Dr. Miller has never prescribed Aredia or Zometa. Dr. Miller's treatment notes do not reflect that Baldwin ever informed him that she was being

treated for cancer at any point before Baldwin was diagnosed with osteonecrosis of the jaw.

II. Discussion

A moving party is entitled to summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a).

Under Missouri law, Winter must prove two elements of causation in her failure-to-warn case. First, she must show that Baldwin's injuries were caused by the product from which the warning was missing. *Arnold v. Ingersoll-Rand Co.*, 834 S.W.2d 192, 194 (Mo. 1992). Second, Winter must show that "a warning would have altered the behavior of the individuals involved in the accident." *Id*. Both Novartis and Winter claim they are entitled to summary judgment on this second element of causation.

A. Novartis's Motion for Summary Judgment

Novartis argues that the uncontroverted facts demonstrate that Winter cannot prove the causation element of her failure-to-warn claims. Winter argues that the multidistrict litigation ("MDL") court already rejected this argument in Novartis's motion for summary judgment before that court in this same litigation, and that the Court should refuse to entertain the argument under the law-of-the-case-doctrine. *See Deutsch v. Novartis Pharmaceuticals Corp.*, 768 F. Supp. 2d 420, 428-2 (E.D.N.Y. 2011) ("[Law of the case] is equally applicable, if not more so, to decisions by an MDL transferee court."). That doctrine "posits that when a court decides a rule of law, that decision should continue to

govern the same issues in subsequent stages in the same case." *Arizona v. California*, 460 U.S. 605, 618 (1983). Novartis argues that law of the case does not apply to denials of summary judgment and, regardless, is only a discretionary doctrine. Regardless, principles of efficiency and comity make the Court hesitant to disturb the MDL court's ruling as "doing so in the absence of a significant change of circumstances would frustrate the purposes of centralized pretrial proceedings." Manual for Complex Litigation, § 20.133 (4th ed. 2004).

Although Novartis relies for its motion on the deposition of Dr. Hueser, which it conducted after the MDL court's rulings, that does not provide compelling grounds to disturb the MDL decision. This is because the MDL judge also found there was a genuine issue of material fact as to whether different warnings would have changed Dr. Miller's behavior. [Doc. # 109-1 at 9]. Dr. Hueser's deposition does not undermine this holding, so it makes no difference to the MDL court's ruling on this issue.

Further, even if the Court were to consider de novo Novartis's claim, Novartis would not be entitled to summary judgment. Novartis argues that under the learned intermediary doctrine, it only had a duty to inform Dr. Hueser, and not Baldwin, of the side effects of its medication. Novartis also argues that because Dr. Hueser testified that he never read the labels for Novartis's medication, Winter cannot show that any inadequacy in those labels caused Baldwin's injury. That is, because Dr. Hueser made himself ignorant of the contents of Novartis's labels, any adequate warnings on those labels would not have been communicated to Baldwin or factored into Dr. Hueser's

treatment of Baldwin. Because causation is a factor of Winter's claims, Novartis argues this interruption in causation entitles Novartis to summary judgment.

But even assuming Novartis's claims are true, Winter has still shown that genuine issues of material fact exist as to causation on her claims. First, Dr. Hueser has testified that he did not read the package inserts for Novartis's medication because Novartis produced these inserts in a way that made them useless to practitioners. Further, Winter has argued that Novartis had a duty to reflect the known side effects of its medication in articles and communications through sales representatives, both of which could have reached Dr. Hueser and changed the course of events despite his not reading package inserts. [Doc. # 109 at 33]. In fact, Winter claims Novartis actively tried to suppress information in medical literature about these side effects. [Doc. # 109 at 33].

Novartis expressly states that its other two requests for summary judgment – on Winter's claim for strict liability and for implied warranty of merchantability – rely on this same causation analysis. [Doc. # 102 at 24]. Because genuine issues of material fact exist as to causation, Novartis is not entitled to summary judgment on any of Winter's claims.

B. Winter's Motion for Summary Judgment

Winter argues that she is entitled to summary judgment on the issue of Novartis's affirmative defense of the learned intermediary. Novartis claims that it is not asserting an affirmative defense of learned intermediary. Thus, Winter's motion for summary judgment on this defense is denied as moot.

Winter also appears to argue that she is entitled to summary judgment on the issue of the adequacy of any warnings by Novartis. Thus, if the Court grants Winter's motion, Winter will have established "that a warning would have altered the behavior of the individuals involved in the accident." *Arnold v. Ingersoll-Rand Co.*, 834 S.W.2d 192, 194 (Mo. 1992).

To the extent Winter argues that she is entitled to summary judgment on the adequacy of its warnings to Dr. Hueser, her argument has no merit. The parties dispute what information Novartis provided to Dr. Hueser and when, and the adequacy of that information is a question for the jury. Further, Novartis has produced evidence that Dr. Hueser never read the package inserts for Novartis's medications, which would rebut any presumption that Dr. Hueser would have heeded an adequate warning. Thus, genuine issues of material fact exist as to the adequacy of warnings by Novartis to Dr. Hueser.

Winter also appears to argue that she is entitled to summary judgment on the adequacy of Novartis's warnings to Baldwin's dentist, Dr. Miller. The parties agree that Novartis never provided any warnings to Dr. Miller. The parties dispute whether Novartis had any duty to warn Dr. Miller, who the parties agree has never prescribed Aredia or Zometa, such that a failure to warn Dr. Miller adequately would support a failure-to-warn claim.

Winter argues that the Third Restatement of Torts created a duty in Novartis to inform Dr. Miller of the side effects of its drug because Dr. Miller was a "health-care related provider[] who [was] in a position to reduce the risks of harm in accordance with

the instructions or warnings" that Novartis provided to prescribing physicians. RESTATEMENT (THIRD) OF TORTS, PROD. LIAB. § 6(d)(1) (1998). Winter further argues that Missouri employs a "heeding presumption" in failure-to-warn cases, entitling Winter to a rebuttable presumption that if Novartis had properly warned Dr. Miller about the risks of its medication, Dr. Miller would have protected Baldwin from any harm from those side effects. *See Arnold v. Ingersoll-Rand Co.*, 834 S.W.2d 192, 194 (Mo. 1992). According to Winter, because Novartis had a duty to warn Dr. Miller, and because the parties agree Novartis provided no warning to Dr. Miller, the heeding presumption applies to entitle Winter to summary judgment as to the second element of causation on her failure-to-warn claim.

Novartis disputes whether Missouri applies or would apply section 6 of the Third Restatement. The Court need not resolve that legal issue at this point, because Novartis has also presented evidence that rebuts the heeding presumption and creates a genuine issue of material fact as to causation. Specifically, Novartis has produced evidence that Dr. Miller was not aware that Baldwin was being treated for cancer until after Baldwin developed osteonecrosis of the jaw. Thus, even if Novartis adequately warned Dr. Miller of the side effects of its medications, Dr. Miller may not have known to apply that information to Baldwin and would not have treated her any differently. Even if Section 6 applies to this case and everything else is as Winter claims, this genuine issue of material fact would still exist, and this precludes summary judgment for Winter on the adequacy of warnings to Dr. Miller.

III. Conclusion

Accordingly, it is hereby ORDERED that Novartis's motion for partial summary judgment [Doc. # 101] is DENIED and Winter's motion for summary judgment [Doc. # 105] is DENIED.

s/ Nanette K. Laughrey
NANETTE K. LAUGHREY
United States District Judge

Dated: October 20, 2011
Jefferson City, Missouri